Application No. 09/449,851

MARKED-UP COPY OF AMENDED CLAIMS:

1. (Fourth Amended) A taste masked formulation which rapidly releases in the stomach of a patient comprising:

a drug-containing core;

a taste masking layer composed of a material which is generally insoluble in saliva at a neutral to basic pH and completely soluble in saliva at a pH of less than about 6.5; and

a spacing layer surrounding said core and substantially completely sequestering said core from said taste masking layer and being capable of rapidly exposing said core when exposed in the stomach of a patient; said taste masking layer preventing exposure of said spacing layer in the mouth of a patient for a period of at least about 20 seconds after being placed into the mouth and being capable of rapidly exposing said spacing layer when in the stomach of a patient; wherein the taste-masked formulation disintegrates in the mouth of a patient in less than 90 seconds to form a suspension of particles; wherein the coated drug-containing core generally has a diameter of no larger than 1,500 microns.

14. (Fourth Amended) A dosage form intended for direct oral administration, comprising:

an effective amount of at least one drug, said drug present in the cores of coated particles, said cores including a taste masking layer composed of a material which is generally insoluble in saliva at a neutral to basic pH and completely soluble in saliva at a pH of less than about 6.5; and

a spacing layer surrounding said core and substantially completely sequestering said core from said taste masking layer and being capable of rapidly exposing said core when exposed in the stomach of a patient; said taste masking layer preventing exposure of said spacing layer in the mouth of a patient for a period of at least about 20 seconds after being placed into the mouth and being capable of rapidly exposing said spacing layer when in the stomach of a patient; and

at least one pharmaceutically acceptable excipient provided in an amount of between greater than zero and less than 100%, based on the weight of the finished dosage form; wherein the taste-masked formulation disintegrates in the mouth of a patient in less

than 90 seconds to form a suspension of particles;. wherein the coated drug-containing core generally has a diameter of no larger than 1,500 microns.

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## REMARKS

Claims 1, 4-18, and 21-25 were pending in the present application. Claims 1 and 14 are amended.

Support for the amendments to claims 1 and 14 can be found, *inter alia*, on page 13, lines 26-28 of the original specification. Applicants contend that the amendments to claims 1 and 14 are fully supported by the original specification and do not raise any issue of new matter. A request for continued examination is concurrently filed with the present Amendment. Therefore, entry of the Amendment is respectfully requested. Upon entry of this Amendment, claims 1, 4-18, 21-27 will be under examination.

The undersigned wishes to thank Examiner Pulliam for the courtesies extended by her during a telephone interview on August 5, 2002. During that interview, the claim amendments proffered hereby were discussed and the Examiner indicated that she was favorably disposed to such claims.

### REJECTIONS UNDER 35 U.S.C §103(a)

Claims 1, 4 to 18 and 21 to 25 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kais. In order to expedite the prosecution of the present application, Applicants hereby amended claims 1 and 14 to positively recite that the taste masked formulation and dosage form "disintegrates in the mouth of a patient in less than 90 seconds to form a suspension of particles."

Applicants respectfully submit that Kais does not teach or suggest the subject matter of claims 1, 4-18 and 21-25, as amended. Specifically, Kais does not provide a teaching, suggestion or motivation to a skilled artisan to produce the claimed taste masked formulations and, in particular, formulations wherein the coated drug-containing core has a diameter of no larger than 1,500 microns and disintegrates in the mouth of a patient in less than 90 seconds.

Furthermore, without looking at the disclosure of the present application (which is not permissible), a person of ordinary skills in the art would not know from Kais how to obtain the claimed formulation having the advantages specified in the claims, e.g., "disintegrates in the mouth of a patient in less than 90 seconds to form a suspension of particles," and "capable of rapidly exposing said spacing layer in the stomach of a patient."

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In addition, the disclosure of Kais, as a whole, teaches away from the present invention, which is a strong indicia of nonobviousness. In fact, Kais achieved its stated advantages, as recited in column 5, lines 22-25, that "the coating can also be chosen so that it remains largely intact through the stomach, thereby avoiding gastric disturbances which are commonly associated with use of dioctyl sulfosuccinate as a medicinal drug." To the contrary, Applicant's formulation and dosage form "disintegrates rapidly in the mouth of a patient to form a suspension of particles " and contains coated-drug containing cores having " a diameter of no larger than 1,500 microns."

Therefore, claims 1, 4-18 and 21-25, as amended, are nonobvious over Kais. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested. In view of the amendments, Applicants believe that the present application is in condition for allowance. Entry of this Amendment, and favorable action in the form of a Notice of Allowance with respect to claims 1, 4-18 and 21-25 are respectfully requested.

As being discussed in the August 5, 2002 telephone interview, the Examiner is encouraged to call the undersigned if there is any issue, which would prevent the issuance of a Notice of Allowance.

No fee other than the one month extension of time fee is required. However, if any other fee is required the examiner is authorized to charge such fee to our Deposit Account No. 12-1095.

Date: August 5, 2002

Respectfully submitted,

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